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10/768,565

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Karla Weaver

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Patrick J. Fay, Esq.
FAY KAPLUN & MARCIN, LLP
Suite 702
150 Broadway
New York, NY 10038

EXAMINER

STIGELL, THEODORE J

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/768,565
Filing Date: January 29, 2004
Appellant(s): WEAVER ET AL.

Oleg Kaplun
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 12/26/2007 appealing from the Office action mailed 7/2/2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,707,357

Mikhail et al.

01-1998

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

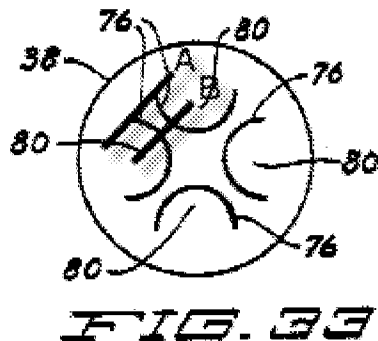
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-21 are rejected under 35 U.S.C. 102(b) as being anticipated by Mikhail (5,707,357).

In regards to claim 1, Mikhail discloses a pressure actuated valve (36) for controlling the flow of fluid through a medical device (10) comprising a housing (14) including a lumen extending therethrough, and a flow control membrane (38) extending across the lumen to control the flow of fluid through the lumen, the membrane including a plurality of slits (76, see at least Figures 21-35) extending therethrough, wherein when the membrane is acted upon by a pressure of at least a threshold magnitude (the examiner is interpreting “pressure” to mean any type of force exerted upon a surface including a force exerted by fluid and squeezing, etc.), the slits open to permit flow through the lumen (see col. 22, lines 38-62) and, when not acted upon by a pressure of at least the predetermined magnitude, the slits are maintained closed by the biasing force applied thereto by the membrane to prevent flow through the lumen (valve 36 is normally biased in a closed position), wherein each of the slits extends between end portions thereof along a curve (there are multiple embodiments in Figs. 21-35 with a plurality of curved slits, see at least Figs. 32 and 33) and wherein a distance between a first end portion of one slit and the first end portions a second slit is the minimum

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distance between the first and second slits (the examiner is defining the "end portions" of the slits as the area between points A and B in the figure shown below, at point B of the end portion is smallest distance between the two slits).



In regards to claims 2-9, Mikhail discloses a valve wherein the first slit extends along a portion of a curve and the second slit extends along a portion of a curve which is substantially a mirror image of the curve (see at least Figs. 28 or 31), and wherein the valve further includes a third slit with a different radius of curvature (see at least Fig. 28), wherein the first and second slits are disposed symmetrically about a line of symmetry (see at least Figs. 28 and 31), wherein the membrane can be elliptical or circular (see column 27, lines 60-67), and wherein the first and second slits are spaced from one another so that the edges of each slit do not contact each other under any condition.

Claims 10-16 recite substantially the same limitations as claims 1-9 and therefore the examiner maintains the same interpretation provided above. Claim 10 does further recite that the membrane is a "substantially planar elastic membrane". The examiner is interpreting "substantially planar" to mean substantially lying in a plane, which the

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membrane (38) certainly does. Claims 10-16 further recite that the elastic membrane is polymeric. Mikhail discloses to use elastic polymers to make pieces of the device (see column 18, lines 45-67).

Claims 17-19 recite substantially the same limitations as claims 1-16 and therefore the examiner maintains the same interpretation provided above. Claim 17 does further recite that the device is a dialysis catheter which the examiner is not assigning much patentable weight thereto. The Mikhail device could be used as a crude dialysis catheter if it had to be. In regards to claims 19, the examiner is interpreting these limitations to be mostly functional. There is no specific magnitude recited that corresponds to the "pressure" exerted by the dialysis machine and therefore the "pressure" could be any pressure. The examiner maintains that there is a fluid pressure that is capable of opening the slits (76) as this feature is inherent to almost any medical slit valve.

Claims 19-20 recite substantially the same structural limitations as claims 1-19 and therefore the examiner maintains the same interpretation provided above. Claims 19-20 further recite that the pressure is a "flow pressure". The examiner maintains that there is a flow pressure strong enough to open the slits (76) of Mikhail even though Mikhail is not necessarily designed to operate in such a manner.

(10) Response to Argument

Applicant's arguments filed 12/26/2007 have been fully considered but they are not persuasive.

In response to the applicants' argument that Mikhail does not disclose a "pressure actuated valve" including a flow control membrane "including a plurality of slits extending therethrough, wherein when the membrane is acted upon by a pressure of at least a threshold magnitude, the slits open to permit flow through the lumen", the examiner respectfully disagrees. The applicants argue that since the Mikhail valve (36) is designed to be opened and closed by squeezing the membrane and not designed to open in response to "fluid" pressure, the limitation recited above is not anticipated. The examiner notes, however, that there is no limitation for "fluid" pressure recited in claim 1 or its dependent claims. The applicants further argue against this position by pointing out that the specification only describes "fluid" pressures and therefore the "pressure" recited in claim 1 can only refer to fluid pressure. This is not found to be persuasive because although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The examiner is interpreting "pressure" to mean any type of force exerted upon a surface including a force exerted by fluid and squeezing, etc. It is clear from the specification and drawings of US 5,707,357 that Mikhail does disclose a "pressure actuated valve" which opens and closes in response to a predetermined pressure (manual pressure).

Furthermore, even if the claims did recite that the slits opened and closed in response to "fluid pressure", the examiner maintains that Mikhail still anticipates the claims. It is the examiner's position that there is inherently a fluid pressure at which the slits (76) of Mikhail would open. The applicants counter this argument by contending

that if such a pressure does exist, it would represent a failure of the valve indicating a defect or loss of structural integrity. The examiner maintains that this argument is conclusory and is not supported by the disclosure of Mikhail. The valve of Mikhail has to be resilient and elastic because it is designed to be opened and closed multiple times and still maintain a fluid seal after considerable use. It is then logical to assume that if a fluid pressure is exerted on the membrane (38) that is strong enough to open the slits just enough for a small amount of fluid to pass through, the slits, being elastic and resilient, will not lose structural integrity and will still maintain a fluid seal in the closed position.

The applicants' further argue that Mikhail does not disclose the limitation of "wherein each of the slits extends between end portions thereof along a curve and wherein a distance between a first end portion of a first one of the slits and a first end portion of a second one of the slits is a minimum distance between the first and second slits" as is recited in claim 1. The applicant argues that this limitation is shown in Figure 5, but the examiner reminds the applicants that limitations from the drawings cannot be read into the claims either. The examiner maintains that Mikhail does disclose this limitation. See the figure reproduced above in the rejection section. The examiner maintains that the end portion of a slit is the area of the slit from the end (point A) to around halfway to the middle (point B). At point B, the slits are a minimum distance from each other.

The applicants have presented the same arguments for claim 10 as were presented for claim 1. The examiner maintains the counter arguments provided above.

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Applicants further argue that the “dome-type” valve of Mikhail is not “substantially planar”. The examiner is interpreting “substantially planar” to mean substantially lying in a plane, which the membrane (38) certainly does.

The applicants have presented the same arguments for claim 17 as were presented for claim 1. The examiner maintains the counter arguments provided above.

Claims 20 and 21 are the only claims that recite a “flow pressure”, but the examiner maintains that there is inherently a “flow pressure” that will open the slits of Mikhail. See the arguments provided above.

In conclusion, the examiner maintains that claims 1-21 are anticipated by Mikhail et al. (5,707,357).

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner’s answer.

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For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Theodore J Stigell/

Examiner, Art Unit 3763

Conferees:

Robin O. Evans

/Robin O. Evans/

TQAS, TC 3700

Nicholas D. Lucchesi

/Nicholas D Lucchesi/

Supervisory Patent Examiner, Art Unit 3763